POLICY MANUAL

CHAPTER: 2
SECTION: 31.5
TITLE: SIMULTANEOUS PANCREAS-KIDNEY (SPK), PANCREAS AFTER KIDNEY (PAK) AND PANCREAS TRANSPLANT ALONE (PTA)

AUTHORITY: 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.4(e)(5)

I. EFFECTIVE DATE

A. October 1, 1995, for SPK transplants.

B. January 1, 1996, for PAK and PTA transplants.

II. PROCEDURE CODE(S)

CPT codes: 48160 and 48550-48556

III. POLICY

A. Pre-authorization is required for simultaneous pancreas-kidney (SPK), pancreas after kidney (PAK), and pancreas transplant alone (PTA) transplantation. The criteria contained in this policy must be followed.

B. Medically necessary services and supplies related to SPK, PAK, and PTA transplantation are cost shared when the transplantation is performed at a Medicare-certified, a TRICARE-certified renal or pancreas transplantation center, or a pediatric facility that is certified as a pancreas transplantation center on the basis that the center belongs to a pediatric consortium program.

C. Benefits are allowed for beneficiaries who:

1. are suffering from concomitant, Type I diabetes mellitus that is resistant to exogenous therapy and end stage chronic renal disease, and hypoglocemia unawareness;

2. have exhausted more conservative medical and surgical treatments for Type I Diabetes Mellitus and renal disease;

3. have a realistic understanding of the range of clinical outcomes that may be encountered; and

4. plan for long-term adherence to a disciplined medical regimen that is feasible and realistic.

D. For a pre-authorized patient, medically necessary services and supplies related to SPK, PAK, and PTA may be cost shared for:

1. evaluation of a potential candidate's suitability for SPK, PAK, and PTA transplantation whether or not the patient is ultimately accepted as a candidate for transplantation;

2. pre and post-transplantation inpatient hospital and outpatient services;

3. pre and post-operative services of the transplant team;

4. the donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center;

5. the maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met;

6. donor costs;

7. blood and blood products;

8. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the medical community. Myocophenolate Mofetil (Cellcept) and Tacrolimus (Prograf) for the prophylaxis of organ rejection in patients receiving SPK, PAK, and PTA are covered;

9. complications of the transplant procedure, including inpatient care, management of infection, and rejection episodes; and

10. periodic evaluation and assessment of the successfully transplanted patient.

11. Transportation of the patient by air ambulance may be cost shared when determined to be medically necessary (see Chapter 2, Section 32.1, *Ambulance Service*).

12. Benefits are allowed for hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

13. Benefits are allowed for DNA-HLA tissue typing determining histo-compatibility.

IV. POLICY CONSIDERATIONS

A. Pre-authorization or retrospective authorization of SPK, PAK, and PTA must meet the following two requirements.

1. patient meets (or as of the date of transplantation, would have met) patient selection criteria, and

2. transplantation facility is (or as of the date of transplantation, would have been) Medicare-certified, a TRICARE-certified renal or pancreas transplantation center, or a pediatric facility that is certified as a pancreas transplantation center on the basis that the center belongs to a pediatric consortium program.

B. In those cases where the beneficiary fails to obtain pre-authorization, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain pre-authorization.

C. Effective for admissions on or after October 1, 1999, SPK, PAK, and PTA transplantations will be reimbursed under the appropriate DRG. Claims for admission prior to October 1, 1999, shall be reimbursed based on billed charges.

D. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation may be cost shared.

E. Benefits will be allowed for donor costs (see Chapter 2, Section 31.1, *Donor Costs*).

F. Charges from the donor hospital (see Chapter 2, Section 31.1, *Donor Costs*).

G. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately in the name of the patient (see Chapter 2, Section 31.1, *Donor Costs*).

H. When a patient is discharged (less than 24-hours) due to circumstances that prohibit the authorized transplant, such as the available organ is found not suitable, all charges will be cost shared on an inpatient basis. When admitted, the expected stay was for more than 24 hours.

V. EXCEPTIONS

A. SPK, PAK, and PTA transplants performed on an emergency basis in an unauthorized renal or pancreas transplant facility may be cost shared only when the following conditions have been met:

1. the unauthorized center **must** consult with the nearest Medicare authorized renal or pancreas transplantation center regarding the transplantation case, and

2. it must be documented by the transplant team physician(s) at the authorized renal or pancreas transplantation center that the transfer (to the authorized renal transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

B. This policy does not apply to beneficiaries who become eligible for Medicare coverage due to isolated renal disease. This policy applies only to those individuals suffering from concomitant Type I Diabetes Mellitus and renal failure.

VI. EXCLUSIONS

A. Services/supplies provided at no cost or if the beneficiary (or sponsor) has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center. [38 CFR 17.272(a)(1)]

B. Services/supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure). [38 CFR 17.272(a)(13)]

C. Services, supplies or devices, even those used in lieu of the transplantation, when determined to be related or integral to an experimental/investigational (unproven) procedure, may not be cost shared (see Chapter 2, Section 16.5, *Experimental/Investigational (Unproven) Procedures).* [38 CFR 17.272(a)(14)]

D. Pre or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members). [38 CFR 17.272(a)(4)]

E. Transportation of an organ donor or cadaver. [38 CFR 17.272(a)(59)].

F. Administration of an experimental or investigational (unproven) immunosuppressant drug that is not FDA approved or has not received CHAMPVA approval as an appropriate "off label" drug indication (see Chapter 2, Section 30.8, *Immunosuppression Therapy*).

G. SPK, PAK, and PTA transplantation is excluded when the following contraindications exist:

1. active alcohol or other substance abuse;

2. amputation due to vascular compromise;

3. malignancies metastasized to or extending beyond the margins of the kidney and/or pancreas; and

4. significant systemic or multisystemic disease (other than pancreatic-renal dysfunction) that limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

H. Pancreatic islet transplantation.

I. Significant coronary artery disease.

END OF POLICY